Remarks

The claim rejections in the prior Office Action have been repeated. All rejections are traversed.

Claims 1-4, 8-11, 13-17, 21-23, 25, and 27-29 (all of the pending claims) are rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement.

Claims 1, 2, 8, 9, and 29 are rejected under 35 USC 103(a) as being obvious over U.S. Patent No. 6,007,833 to Chudzik et al. (the '833 patent). This rejection is new but the only difference is that the claims are now rejected under 103(a) instead of 102(e).

Claims 3, 4, 10, 11, 13-17, 21-23, 25, 27, and 28 are rejected as obvious over the '833 patent in view of U.S. Patent No. 6,179,862 to Sawhney et al. (the '862 patent).

The Written Description Rejection

The claims state that the composition includes a "crosslinking initiator that is not bound to a macromer or another polymer". The Examiner believes that this element is not sufficiently taught by the specification.

It appears that the Examiner is confused by the claim wording and that an explanation will clear up this confusion. The Examiner objects to the recitation of "the initiator not bound to another polymer", stating that "another polymer" is not disclosed in the specification. The claim actually reads "initiator not bound to a macromer or another polymer"- meaning that the initiator is not bound to the macromer or any polymer other than the macromer. The macromers are polymers (see the definition of macromer on page 4- a macromer is a "macromolecular monomer"). Thus the phrase "another polymer" modifies and refers to the macromer, not a second polymer taught in the specification.

If this explanation does not satisfy the Examiner, applicants are willing to amend the claim to read "crosslinking initiator that is not bound to a macromer or any other ~~another~~ polymer". As discussed in detail in the previous response, the claims at issue are drawn to the use of an unbound initiator, and the specification clearly enables unbound initiator.

The rejection of claims 1, 2, 8, 9, and 29 over the '833 patent

The '833 patent does not teach OR SUGGEST unbound initiator

The '833 patent teaches a crosslinkable macromer system that can be used as a wound dressing. The system includes two or more polymerizable groups that are pendant on (attached to) a macromer or polymer and one or more initiator groups that are pendant on (attached to) a macromer or polymer. The Examiner agrees that the "initiator group is present as either a pendant group on a polymerizable macromer, or pendant on separate, non-polymerizable polymer backbone" (See the Office Action of October 27 on page 4). Since Applicants' claims are drawn to an unbound initiator (a "crosslinking initiator that is not bound to a macromer or another polymer"), this reference does not teach the claimed invention. Moreover, this reference does not suggest use of an unbound initiator and in fact teaches away from use of an unbound initiator.

The '833 patent specifically teaches that free initiators should be avoided as they can present issues of toxicity, efficacy, and solubility (see col. 2, lines 15-20). To this effect, the initiators are bound to the backbone of either the polymer or macromer.

The Examiner points to col. 15, lines 28-31 as support for the proposition that '833 teaches unbound initiator. However, Example 12 is comparing polymer bound initiator with non-polymer-bound initiator and finds that the non-polymer-bound initiator is **NOT AS GOOD**. The '833 patent doesn't state that either polymer bound or non-polymer bound can be used- it states just the opposite. The patent states that unbound initiators should be avoided for various reasons such as toxicity and then shows in Example 12 that they don't work as well anyway.

In the response to arguments section on page 6 of the office action, the Examiner states that the phrase that the initiator "can be" bound to the polymeric backbone indicates that it "can also not be" bound to the backbone. Applicants have no objection to this argument, but do not agree that this refers to unbound initiator. Rather it means that the initiator can instead be bound to another part of the polymer (not the backbone) or to another polymer.

The Examiner further argues that the disclosure in example 12 that unbound initiator doesn't work as well- and the disclosure in '833 to avoid unbound initiator for other reasons such as toxicity does not teach away from using non-bound initiator. To the contrary, this is a text book example of "teaching away".

See also the definition of initiator (col. 4, lines 49-53): ""initiator group" shall refer to a chemical group capable of initiating a free radical reaction, present as either a pendent group on a polymerizable macromer or pendent on a separate, non-polymerizable polymer backbone"

The '833 patent does not teach OR SUGGEST spray delivery

Moreover, the '833 patent does not teach or suggest a wound dressing formed by spray delivery of a liquid composition. The Examiner's argument is that the '833 patent teaches spray delivery because it does not teach any method of delivery at all ("US '833 teaches the liquid delivery of the composition without excluding or specifying any method of delivery, thus the spraying the [sic] liquid composition into the wound is inclusive in the reference teaching."). In fact, the '833 patent does teach several methods of delivery, none of which are spray delivery- it teaches applying the liquid composition via a catheter (see col. 10, lines 27-29); via syringe (see col. 16, lines 52-59); and via dip coating (see Examples 16 and 17).

A wound dressing formed by spray application of a composition offers several advantages over application of a liquid composition via syringe, catheter, or dipping. See page 3, lines 1-12 of the specification. Spray delivery can increase the penetration of the polymer into the wound area thereby potentially making the delivery of active ingredients more efficient. Penetration of the polymer into the wound bed may also aid in debridement of the wound during dressing changes to accelerate the wound healing process. With spray delivery of an in situ polymerizing polymer, a thin coating can be achieved with excellent coverage of the treated area.

<u>The rejection of claims 3, 4, 10, 11, 13-17, 21-23, 25, 27, and 28 over the '833 patent in view of the '862 patent</u>

The '833 patent

The '833 patent is discussed above. The Examiner states (page 6 of the Office Action dated 10/27/05) that the '833 patent does not teach spray delivery (as claimed in claims 3, 4, 14-17, 21, and 22); NO as an active agent (claims 10 and 23); redox irradiation (sic) (claims 13 and 25); and debridement of the wound (claim 12).

However, the Examiner next states that the '833 patent teaches spray delivery since it doesn't exclude or specify any method of delivery, and that it teaches NO as an active agent since it teaches delivery of antithrombic drugs. The Examiner also states that the '833 patent

teaches UV irradiation to initiate polymerization- which is assumed to be supposedly relevant to redox "irradiation". None of these arguments are valid.

The '862 patent

The '862 patent teaches a method for forming a tissue adherent barrier in situ using a sprayer to deliver crosslinkable fluids. One of the fluids specifically described as suitable in the method is a solution of macromer. However, the only macromer specifically discussed is a PEG-oligolactyl-diacrylate macromer which has a PEG core unit, a polyhydroxy acid extension on each end, and an acrylate end group on each end. PEG has only two hydroxyl groups - at each terminus- to which the crosslinkable acrylates can be fastened (see col. 6, ll. 18-32). The claimed macromers, on the other hand, because they are based on PVA, have crosslinkable groups on pendant chains- chains hanging from the backbone. A tremendous advantage of using PVA rather than PEG is that there are many available hydroxyl groups to which crosslinkable or other groups can be attached, and not just two, as in PEG. Thus, the use of PVA as the backbone of the macromers claimed in the present application offers advantages unexpected and unforeseen by the prior art.

The '862 and '833 patents are cited in combination as rendering the claims obvious. The Examiner argues that the '833 patent teaches the macromers, which is not true, as discussed above. The Examiner states that the '833 patent teaches the initiator can be not bound to the macromer (in other words that they can be bound to the polymer). The Examiner's argument does not take into account that the claims recite an initiator that is "not bound to a macromer or another polymer".

There exists no reason to combine the teachings of the references. In fact, as discussed previously, the '833 patent teaches away from the invention recited in the claims because it specifically teaches using a bound initiator. Moreover, even if the references are combined, the claimed invention does not result. The combined patents do not teach a wound dressing formed by spraying a PVA macromer having one or more pendant crosslinkable groups and using an unbound initiator.

The law requires that there be- in the references themselves- some motivation to combine the references. Nowhere does the '833 patent suggest that it would be beneficial or even possible to spray the composition taught therein and form a wound dressing. Nowhere does the

'862 patent teach that it would be beneficial to use a PVA macromer having one or more pendant acrylamide groups containing olefinically unsaturated groups (assuming that this were even taught by the '833 patent).

Specific dependent claims

Claims 4 and 17

Neither the '833 nor the '862 patent teaches the use of a pump spray device. The devices taught in the '862 patent rely upon gas discharge.

Claims 10 and 23

Neither patent teaches the delivery of nitric oxide (NO) to the wound using the wound dressing.

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